

Message Text

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PAGE 01 ROME 06945 150732Z
ACTION EB-08

INFO OCT-01 EUR-12 IO-14 ISO-00 COME-00 L-03 /038 W
-----030040 160821Z /13

R 141245Z APR 78
FM AMEMBASSY ROME
TO SECSTATE WASHDC 2108
INFO AMEMBASSY BRUSSELS
US MISSION GENEVA 1312
AMCONSUL MILAN

UNCLAS ROME 6945

USEC, USMTN

PASS USDOC - PATENT AND TRADEMARK OFFICE

E.O. 11652: N/A
TAGS: ETRD, MTN, PGOV, IT
SUBJ: ITALIAN CONSTITUTIONAL COURT RULING ON PHARMACEUTICAL
PATENTS

REF: A. STATE 086131, B. STATE 91168, C. GENEVA 05474

1. THIS WILL CONFIRM THAT ITALIAN CONSTITUTIONAL COURT RULING NO. 20 RENDERED ON MARCH 9, 1978, FOUND UNCONSTITUTIONAL ARTICLE 14 OF ITALY'S BASIC PATENT LAW. ARTICLE 14 EXPRESSLY PROHIBITED PATENTING OF "MEDICINALS OF ANY KIND". EFFECT OF RULING IS TO PLACE PHARMACEUTICALS UNDER PATENT PROTECTION FOR FIRST TIME SINCE 1939, WHEN BASIC PATENT LAW WAS ENACTED.

2. EFFECTIVE DATE OF COURT RULING IS MARCH 22. CONSEQUENTLY, SOME 1,280 DRUG PATENT APPLICATIONS REPORTED TO HAVE BEEN FILED IN ITALY IN RECENT YEARS, AS WELL AS DRUG PATENT APPLICATIONS FILED ON OR AFTER MARCH 22, ARE REQUIRED TO BE PROCESSED AND, EVENTUALLY, GRANTED PATENTS IN ACCORDANCE WITH 1939 PATENT LAW. ARTICLE 14 HAS BEEN EXPUNGED FROM THE LAW. IN THIS CONNECTION,
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SOURCES CONSULTED NOTED THAT FILING DATE IS SIGNIFICANT WITH RESPECT TO CLAIMS AGAINST PATENT INFRINGEMENTS. LATTER CLAIMS ARE USUALLY ADMITTED ONLY FROM DATE OF ISSUANCE, SINCE THAT IS WHEN PATENTING OF AN INVENTION BECOMES PUBLIC INFORMATION.

3. LEGISLATION IS NOT REQUIRED TO IMPLEMENT CONSTITUTIONAL COURT DECISION, WHICH IS FULLY IN EFFECT. REPORT BY ITALIAN

EMBASSY AT WASHINGTON STATING THAT LEGISLATION IS REQUIRED FOR ISSUANCE DRUG PATENTS IS INACCURATE. HOWEVER, ITALIAN GOVERNMENT IS CONSIDERING PROMPT SUBMISSION, FOR URGENT ENACTMENT BY PARLIAMENT, OF SPECIAL DRUG PATENTING LEGISLATION IN ORDER TO PLACE LIMITS ON PROTECTION THEORETICALLY AVAILBLE BECAUSE OF EFFECT OF COURT RULING. PRINCIPAL OBJECTIVES OF SUCH NEW LEGISLATION, AS REPORTED BY EMBASSY'S CONTACTS, ARE: (1) TO PROVIDE FOR COMPULSORY LICENSING OF PATENTED PHARMACEUTICALS TO FIRMS ALREADY PRODUCING IDENTIAL PRODUCTS WHICH THEY ORIGINATED, BUT DID NOT SEEK TO PATENT, AS WELL AS LICENSING TO FIRMS WHICH COULD BE FOUND TO BE PRODUCING "COPIED" DRUGS, IN ORDER TO PERMIT SUCH FIRMS TO CONTINUE IN BUSINESS; AND (2) TO LIMIT PATENTABILITY OF DRUG MANUFACTURING PROCESSES TO A SINGLE, WELL-DEFINED AND RE-PRODUCIBLE PROCESS LEADING TO A DETERMINED DRUG OR CALSS OF WELL-WEFINED ALLIED DRUGS, AND NOT TO GENERIC CHEMICAL FORMULAE WITH VARIABLE COMPONENTS.

4. THE KEY SENTENCE OF THE CONSTITUTIONAL COURT RULING NO. 20, PUBLISHED IN THE OFFICIAL GAZETTE NO. 87 (SPECIAL ISSUE) DATED MARCH 29, 1978, READS AS FOLLOWS: "THE CONSTITUTIONAL COURT DECLARES AS CONSITITUIONALLY ILLEGAL THE FIRST PARAGRAPH OR ARTICLE 14 OR ROYAL DECREE OF JUNE 29, 1939 NO. 1127". LAS NO. 1127 OF JUNE 29, 1939 IS ITALY'S BASIC PATENT LAW. ARTICLE 14 OF THIS LAW STAES "MEDICIANLS OF ANY KIND, INCLUDING THE PROCESSES FOR THEIR PRODUCTION, CANNOT FOR THE OBJECT OF A PATENT". THE ABOVE RULING OF THE CONSTITUTIONAL COURT RESULTED UNCLASSIFIED

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FROM SOME 20 APPEALS AGAINST REJECTION OF DRUG PATENT APPLICATIONS BY THE ITALIAN PATENT OFFICE, ON THE BASIS OF ARTICLE 14 OF THE 1939 PATENT LAW. THESE CASES HAD BEEN BROUGHT BEFORE THE COMMISSION OF PATENT APPEALS. THE LATTER COMMISSION TURNED THE CASES OVER TO THE CONSTITUTIONAL COURT SINCE THE APPEALS CONTAINED JUSTIFIED EVIDENCE THAT ARTICLE 14 OF THE 1939 PATENT LAW WAS UNCONSTITUTIONAL.

5. PATENT LAWYERS CONSULTED BY THE EMBASSY CONFIRMED THAT DRUGS AS WELL AS DRUG MANUFACTURING PROCESSES ARE NOW PATENTABLE IN ITALY. THEY INDICATED, HOWEVER, THAT IT MAY TAKE SEVERAL MONTHS BEFORE THE PATENTS ARE ISSUED BECAUSE OF THE LARGE BACKLOG OF PATENT APPLICATIONS PENDING BEFORE THE ITALIAN PATENT OFFICE, AND THE SHORTAGE OF QUALIFIED PERSONNEL. IN VIEW OF THIS SISTUATION, THE AVERAGE TIME NEEDED TO PROCESS A PATENT APPLICA-TION IN ANY FIELD IS REPORTED TO BE NEARLY THREE YEARS.GARDNER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CHEMICAL INDUSTRY, COURT DECISIONS, PATENTS
Control Number: n/a
Copy: SINGLE
Draft Date: 14 apr 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978ROME06945
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780163-0540
Format: TEL
From: ROME
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780454/aaaabuay.tel
Line Count: 110
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: c69801b0-c288-dd11-92da-001cc4696bcc
Office: ACTION EB
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 78 STATE 86131, 78 STATE 91168, 78 GENEVA 5474
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2961984
Secure: OPEN
Status: NATIVE
Subject: ITALIAN CONSTITUTIONAL COURT RULING ON PHARMACEUTICAL PATENTS
TAGS: ETRD, PGOV, IT, MTN
To: STATE USEEC MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/c69801b0-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014